House of Representatives

General Assembly

File No. 399

February Session, 2014

Substitute House Bill No. 5042

House of Representatives, April 7, 2014

The Committee on Commerce reported through REP. PERONE of the 137th Dist., Chairperson of the Committee on the part of the House, that the substitute bill ought to pass.

AN ACT CONCERNING THE REGENERATIVE MEDICINE RESEARCH FUND.

Be it enacted by the Senate and House of Representatives in General Assembly convened:

Section 1. Subsection (a) of section 19a-32d of the 2014 supplement to the general statutes is repealed and the following is substituted in lieu thereof (*Effective October 1, 2014*):

(a) As used in sections 19a-32d to 19a-32g, inclusive, as amended by this act, and section 4-28e, as amended by this act:

(1) "Embryonic stem cell research oversight committee" means a committee established in accordance with the National Academies' Guidelines for Human Embryonic Stem Cell Research, as amended from time to time.

(2) "Cloning of a human being" means inducing or permitting a replicate of a living human being's complete set of genetic material to develop after gastrulation commences.

(3) "Gastrulation" means the process immediately following the blastula state when the hollow ball of cells representing the early embryo undergoes a complex and coordinated series of movements that results in the formation of the three primary germ layers, the ectoderm, mesoderm and endoderm.

(4) "Embryonic stem cells" means cells created through the joining of a human egg and sperm or through nuclear transfer that are sufficiently undifferentiated such that they cannot be identified as components of any specialized cell type.

(5) "Nuclear transfer" means the replacement of the nucleus of a human egg with a nucleus from another human cell.

(6) "Eligible institution" means (A) a nonprofit, tax-exempt academic institution of higher education, (B) a hospital that conducts biomedical research, or (C) any entity that conducts biomedical research or **[**embryonic or human adult stem cell**]** regenerative medicine research.

(7) "Regenerative medicine" means the process of creating living, functional tissue to repair or replace tissue or organ function lost due to aging, disease, damage or congenital defect. Regenerative medicine includes basic stem cell research.

Sec. 2. Section 19a-32e of the general statutes is repealed and the following is substituted in lieu thereof (*Effective October 1, 2014*):

(a) There is established the **[**"Stem Cell Research Fund"**]** "Regenerative Medicine Research Fund", which shall be a separate, nonlapsing account within the General Fund. The fund may contain any moneys required or permitted by law to be deposited in the fund and any funds received from any public or private contributions, gifts, grants, donations, bequests or devises to the fund. **[**The Commissioner of Public Health may**]** The chief executive officer of Connecticut Innovations, Incorporated, (1) shall make grants-in-aid from the fund in accordance with the provisions of subsection (b) of this section, and (2) may enter into agreements with other entities, including, but not

limited to, the government of any state or foreign country for the purpose of advancing research collaboration opportunities for recipients of grants-in-aid under this section.

(b) [Not later than June 30, 2006, the Stem Cell] The Regenerative Medicine Research Advisory Committee established pursuant to section 19a-32f, as amended by this act, shall develop an application for grants-in-aid under this section for the purpose of conducting [embryonic or human adult stem cell] regenerative medicine research and may receive applications from eligible institutions for such grants-in-aid. [on and after said date. The Stem Cell] The Regenerative Medicine Research Advisory Committee shall require any applicant for a grant-in-aid under this section to conduct [stem cell] regenerative medicine research to submit (1) a complete description of the applicant's organization, (2) the applicant's plans for [stem cell] regenerative medicine research and proposed funding for such research from sources other than the state, [of Connecticut,] and (3) proposed arrangements concerning financial benefits to the state [of Connecticut] as a result of any patent, royalty payment or similar rights developing from any [stem cell] proposed research made possible by the awarding of such grant-in-aid. [Said committee shall direct the Commissioner of Public Health] The Regenerative Medicine Research Advisory Committee shall direct the chief executive officer of Connecticut Innovations, Incorporated, with respect to the awarding of such grants-in-aid after considering recommendations from the [Stem Cell] Regenerative Medicine Research Peer Review Committee established pursuant to section 19a-32g, as amended by this act.

(c) Commencing with the fiscal year ending June 30, 2006, and for each of the [nine] fourteen consecutive fiscal years thereafter, until the fiscal year ending June 30, [2015] 2020, not less than ten million dollars shall be available from the [Stem Cell] Regenerative Medicine Research Fund for grants-in-aid to eligible institutions for the purpose of conducting [embryonic or human adult stem cell research, as directed by the Stem Cell Research Advisory Committee established pursuant to section 19a-32f] regenerative medicine research. Any balance of such

amount not used for such grants-in-aid during a fiscal year shall be carried forward for the fiscal year next succeeding for such grants-in-aid.

Sec. 3. Section 19a-32f of the general statutes is repealed and the following is substituted in lieu thereof (*Effective October 1, 2014*):

(a) (1) There is established a **[**Stem Cell**]** Regenerative Medicine Research Advisory Committee. The committee shall consist of the Commissioner of Public Health, or the commissioner's designee, the chief executive officer of Connecticut Innovations, Incorporated, or the chief executive officer's designee, and eight members who shall be appointed as follows: Two by the Governor, **[**one of whom shall be nationally recognized as an active investigator in the field of stem cell research and one of whom shall have background and experience in the field of bioethics**]** who shall have backgrounds and experience in embryonic stem cell or regenerative medicine research; one each by the president pro tempore of the Senate and the speaker of the House of Representatives, who shall have background and experience in private sector **[**stem cell**]** regenerative medicine research and development; one each by the majority leaders of the Senate and House of Representatives, who shall be academic researchers specializing in **[**stem cell**]** regenerative medicine research; one by the minority leader of the Senate, who shall have background and experience in either private or public sector **[**stem cell**]** regenerative medicine research and development or related research fields, including, but not limited to, embryology, genetics or cellular biology; and one by the minority leader of the House of Representatives, who shall have background and experience in business or financial investments. Members shall serve for a term of four years commencing on October first, except that members first appointed by the Governor and the majority leaders of the Senate and House of Representatives shall serve for a term of two years. No member may serve for more than two consecutive four-year terms and no member may serve concurrently on the **[**Stem Cell**]** Regenerative Medicine Research Peer Review Committee established pursuant to section 19a-32g, as amended by this act. All initial

appointments to the committee shall be made by October 1, 2005. Any vacancy shall be filled by the appointing authority.

(2) On and after July 1, 2006, the **[**advisory committee**]** Regenerative Medicine Research Advisory Committee shall include eight additional members who shall be appointed as follows: Two by the Governor, **[**one of whom shall be nationally recognized as an active investigator in the field of stem cell research and one of whom shall have background and experience in the field of ethics**]** who shall have backgrounds and experience in business, law or ethics; one each by the president pro tempore of the Senate and the speaker of the House of Representatives, who shall have background and experience in private sector **[**stem cell**]** regenerative medicine research and development; one each by the majority leaders of the Senate and House of Representatives, who shall be academic researchers specializing in **[**stem cell**]** regenerative medicine research; one by the minority leader of the Senate, who shall have background and experience in either private or public sector **[**stem cell**]** regenerative medicine research and development or related research fields, including, but not limited to, embryology, genetics or cellular biology; and one by the minority leader of the House of Representatives, who shall have background and experience in business or financial investments. Members shall serve for a term of four years, except that (A) members first appointed by the Governor and the majority leaders of the Senate and House of Representatives pursuant to this subdivision shall serve for a term of two years and three months, and (B) members first appointed by the remaining appointing authorities shall serve for a term of four years and three months. No member appointed pursuant to this subdivision may serve for more than two consecutive four-year terms and no such member may serve concurrently on the **[**Stem Cell**]** Regenerative Medicine Research Peer Review Committee established pursuant to section 19a-32g, as amended by this act. All initial appointments to the committee pursuant to this subdivision shall be made by July 1, 2006. Any vacancy shall be filled by the appointing authority.

[(b) The Commissioner of Public Health, or the commissioner's

designee, shall serve as the chairperson of the committee and shall schedule the first meeting of the committee, which shall be held no later than December 1, 2005.**]**

(b) The chief executive officer of Connecticut Innovations, Incorporated, or the chief executive officer's designee, shall serve as chairperson of the Regenerative Medicine Research Advisory Committee.

(c) All members appointed to **[**the**]** said advisory committee shall work to advance **[**embryonic and human adult stem cell**]** regenerative medicine research. Any member who fails to attend three consecutive meetings or who fails to attend fifty per cent of all meetings held during any calendar year shall be deemed to have resigned from **[**the**]** said advisory committee.

(d) Notwithstanding the provisions of any other law, it shall not constitute a conflict of interest for a trustee, director, partner, officer, stockholder, proprietor, counsel or employee of any eligible institution, or for any other individual with a financial interest in any eligible institution, to serve as a member of **[**the**]** said advisory committee. All members shall be deemed public officials and shall adhere to the code of ethics for public officials set forth in chapter 10. Members may participate in the affairs of **[**the**]** said advisory committee with respect to the review or consideration of grant-in-aid applications, including the approval or disapproval of such applications, except that no member shall participate in the affairs of **[**the**]** said advisory committee with respect to the review or consideration of any grant-in-aid application filed by such member or by any eligible institution in which such member has a financial interest, or with whom such member engages in any business, employment, transaction or professional activity.

(e) The **[**Stem Cell**]** Regenerative Medicine Research Advisory Committee shall (1) develop, in consultation with **[**the Commissioner of Public Health**]** Connecticut Innovations, Incorporated, a donated funds program to encourage the development of funds other than state

appropriations for [embryonic and human adult stem cell] regenerative medicine research in [this] the state, (2) examine and identify specific ways to improve and promote for-profit and not-for-profit [embryonic and human adult stem cell] regenerative medicine research and [related] research in related areas in the state, including, but not limited to, identifying both public and private funding sources for such research, maintaining existing [embryonic and human adult stem-cell-related] regenerative medicine-related businesses, recruiting new [embryonic and human adult stem-cell-related] regenerative medicine-related businesses to the state and recruiting scientists and researchers in such field to the state, (3) [establish and] administer, in consultation with the [Commissioner of Public Health] Bioscience Innovation Advisory Committee and Connecticut Innovations, Incorporated, a [stem cell] regenerative medicine research grant program [which] that shall provide grants-in-aid to eligible institutions for the advancement of [embryonic or human adult stem cell] regenerative medicine research in [this] the state pursuant to section 19a-32e, [and] as amended by this act, (4) monitor the [stem cell] regenerative medicine research conducted by eligible institutions that receive such grants-in-aid, and (5) prepare a comprehensive strategic plan for the Regenerative Medicine Research Fund, established pursuant to section 19a-32e, as amended by this act, and grants-in-aid made from said fund that shall include, but need not be limited to, identification of specific methods or strategies to (A) achieve the scientific and economic development objective of said fund, (B) build innovation capacity, and (C) sustain investments of moneys received by said fund.

(f) Connecticut Innovations, Incorporated, shall serve as administrative staff of the [committee] Regenerative Medicine Research Advisory Committee and shall assist [the] said advisory committee in: (1) [developing] Developing the application for the grants-in-aid authorized under subsection [(e) of this section,] (b) of section 19a-32e, as amended by this act; (2) reviewing such applications; [,] (3) reviewing recommendations of the Regenerative Medicine Research Peer Review Committee, established pursuant to

section 19a-32g, as amended by this act; (4) preparing and executing any assistance agreements or other agreements in connection with the awarding of such grants-in-aid; **[**, and (4)**]** (5) developing performance metrics and systems to collect data from recipients of such grants-in-aid; (6) collecting information from recipients of such grants-in-aid concerning each recipient's (A) employment statistics, (B) business accomplishments and performance outcomes, (C) peer review articles and papers published, (D) partnerships and collaborations with other entities, (E) licenses, patents and invention disclosures, (F) scientific progress as it relates to the commercialization of intellectual property funded by such grants-in-aid, (G) efforts to commercialize such intellectual property, and (H) other funds received for research; and (7) performing such other administrative duties as the **[**committee**]** Regenerative Medicine Research Advisory Committee deems necessary.

Sec. 4. Section 19a-32g of the general statutes is repealed and the following is substituted in lieu thereof (*Effective October 1, 2014*):

(a) (1) There is established a **[**Stem Cell**]** Regenerative Medicine Research Peer Review Committee. **[**The**]** Said peer review committee shall consist of five members. **[**appointed by the Commissioner of Public Health. All**]**

(2) On and before September 30, 2014, all members appointed by the Commissioner of Public Health to the committee shall (A) have demonstrated knowledge and understanding of the ethical and medical implications of **[**embryonic and human adult stem cell**]** regenerative medicine research or related research fields, including, but not limited to, embryology, genetics or cellular biology, (B) have practical research experience in **[**human adult or embryonic stem cell**]** regenerative medicine research or related research fields, including, but not limited to, embryology, genetics or cellular biology, and (C) work to advance **[**embryonic and human adult stem cell**]** regenerative medicine research. Members shall serve for a term of four years commencing on October first, except that three members first

appointed by the Commissioner of Public Health shall serve for a term of two years. No member may serve for more than two consecutive four-year terms and no member may serve concurrently on the **[**Stem Cell**]** Regenerative Medicine Research Advisory Committee established pursuant to section 19a-32f, as amended by this act. All initial appointments to **[**the**]** said peer review committee shall be made by October 1, 2005. Any member who fails to attend three consecutive meetings or who fails to attend fifty per cent of all meetings held during any calendar year shall be deemed to have resigned from **[**the**]** said peer review committee.

[(2) The Commissioner of Public Health may appoint such additional members to the Stem Cell Research Peer Review Committee as the commissioner deems necessary for the review of applications for grants-in-aid, provided the total number of Stem Cell Research Peer Review Committee members does not exceed fifteen. Such additional members shall be appointed as provided in subdivision (1) of this subsection, except that such additional members shall serve for a term of two years from the date of appointment.**]**

(3) On and after October 1, 2014, each member appointed by the Commissioner of Public Health pursuant to subdivision (2) of this subsection may serve to the conclusion of his or her current term at which time members shall be appointed by the chief executive officer of Connecticut Innovations, Incorporated, as follows: Members appointed to said peer review committee shall: (A) Have demonstrated knowledge and understanding of the ethical and medical implications of regenerative medicine research or research in a related field, including, but not limited to, embryology, genetics or cellular biology; (B) have practical research experience in regenerative medicine research or research in a related field, including, but not limited to, embryology, genetics or cellular biology; and (C) work to advance regenerative medicine research. Members shall serve for a term of four years, except that three members first appointed by the chief executive officer of Connecticut Innovations, Incorporated, shall serve for a term of two years. No member may serve for more than two consecutive

four-year terms and no member may serve concurrently on the Regenerative Medicine Research Advisory Committee established pursuant to section 19a-32f, as amended by this act. Any member who fails to attend three consecutive meetings or who fails to attend fifty per cent of all meetings held during any calendar year shall be deemed to have resigned from said peer review committee.

(b) All members shall be deemed public officials and shall adhere to the code of ethics for public officials set forth in chapter 10. No member shall participate in the affairs of the committee with respect to the review or consideration of any grant-in-aid application filed by such member or by any eligible institution in which such member has a financial interest, or with which such member engages in any business, employment, transaction or professional activity.

(c) Prior to the awarding of any grants-in-aid for **[**embryonic or human adult stem cell**]** regenerative medicine research pursuant to section 19a-32e, as amended by this act, the **[**Stem Cell**]** Regenerative Medicine Research Peer Review Committee shall review all applications submitted by eligible institutions for such grants-in-aid and make recommendations to the **[**Commissioner of Public Health and the Stem Cell**]** Regenerative Medicine Research Advisory Committee established pursuant to section 19a-32f, as amended by this act, with respect to the ethical and scientific merit of each application.

(d) **[**Peer review committee members**]** Members of the Regenerative Medicine Research Peer Review Committee may receive compensation from **[**the Stem Cell Research Fund, established pursuant to section 19a-32e,**]** Connecticut Innovations, Incorporated, for reviewing grant-in-aid applications submitted by eligible institutions. **[**pursuant to subsection (c) of this section.**]** The rate of compensation shall be established by the **[**Commissioner of Public Health in consultation with the Department of Administrative Services and the Office of Policy and Management**]** board of directors of Connecticut Innovations, Incorporated.

(e) The Regenerative Medicine Research Peer Review Committee

shall establish guidelines for the rating and scoring of such applications. **[**by the Stem Cell Research Peer Review Committee.**]**

(f) All members of **[**the**]** said peer review committee shall become and remain fully cognizant of the National Academies' Guidelines for Human Embryonic Stem Cell Research, as amended from time to time, and shall utilize said guidelines to evaluate each grant-in-aid application. **[**The committee may make recommendations to the Stem Cell Research Advisory Committee and the Commissioner of Public Health concerning the adoption of said guidelines, in whole or in part, in the form of regulations adopted pursuant to chapter 54.**]**

Sec. 5. Section 32-41aa of the 2014 supplement to the general statutes is repealed and the following is substituted in lieu thereof (*Effective October 1, 2014*):

For the purpose of this section and sections 32-41bb to 32-41dd, inclusive, as amended by this act:

[(1) "Administrative costs" means the costs paid or incurred by the administrator, including, but not limited to, peer review costs, professional fees, allocated staff costs and other out-of-pocket costs attributable to the administration and operation of the Connecticut Bioscience Innovation Fund.**]**

[(2)**]** (1) "Administrator" means Connecticut Innovations, Incorporated, in its capacity as administrator of the Connecticut Bioscience Innovation Fund established pursuant to section 32-41cc, as amended by this act.

[(3)**]** (2) "Advisory committee" means the Bioscience Innovation Advisory Committee established pursuant to section 32-41bb, as amended by this act.

[(4)**]** (3) "Early-stage business" means a business that has been in operation for not more than three years and is developing or testing a product or service that is (A) not yet available for commercial release, or (B) commercially available in a limited manner, including, but not

limited to, market testing of prototypes and clinical trials.

[(5)**]** (4) "Eligible recipient" means a duly accredited college or university, a nonprofit corporation or a for-profit start-up or early-stage business.

[(6)**]** (5) "Financial assistance" means any and all forms of grants, extensions of credit, loans or loan guarantees, equity investments or other forms of financing.

[(7)**]** (6) "Return on investment" means any and all forms of principal or interest payments, guarantee fees, returns on equity investments, royalties, options, warrants and debentures and all other forms of remuneration to the administrator in return for any financial assistance offered or provided.

Sec. 6. Subsection (e) of section 32-41bb of the 2014 supplement to the general statutes is repealed and the following is substituted in lieu thereof (*Effective October 1, 2014*):

(e) Notwithstanding any provision of the general statutes, it shall not constitute a conflict of interest for a trustee, director, partner, officer, manager, shareholder, proprietor, counsel or employee of an eligible recipient, or any individual with a financial interest in an eligible recipient, to serve as a member of the advisory committee, provided such trustee, director, partner, officer, manager, shareholder, proprietor, counsel, employee or individual shall abstain from deliberation, action or vote by the advisory committee in specific respect to such eligible recipient. All members of the advisory committee shall be deemed public officials and shall adhere to the code of ethics for public officials set forth in chapter 10.

Sec. 7. Subsections (d) and (e) of section 32-41cc of the 2014 supplement to the general statutes are repealed and the following is substituted in lieu thereof (*Effective October 1, 2014*):

(d) The Connecticut Bioscience Innovation Fund shall be used (1) to provide financial assistance to eligible recipients as may be approved

by the advisory committee pursuant to subsection (e) of this section, and (2) for the repayment of state bonds in such amounts as may be required by the State Bond Commission. **[**, and (3) to pay or reimburse the administrator for administrative costs pursuant to subsection (j) of this section.**]** Such financial assistance shall be awarded to further the development of bioscience, biomedical engineering, health information management, medical care, medical devices, medical diagnostics, pharmaceuticals, personalized medicine and other related disciplines that are likely to lead to an improvement in or development of services, therapeutics, diagnostics or devices that are commercializable and designed to advance the coordination, quality or efficiency of health care and lower health care costs, and that promise, directly or indirectly, to lead to job growth in the state in these or related fields.

(e) All expenditures from the Connecticut Bioscience Innovation Fund, except for **[**administrative costs reimbursed to the administrator pursuant to subsection (j) of this section and**]** amounts required for the repayment of state bonds in such amounts as may be required by the State Bond Commission, shall be approved by the advisory committee. Any such approval shall be (1) specific to an individual expenditure to be made, (2) for budgeted expenditures with such variations as the advisory committee may authorize at the time of such budget approval, or (3) for a financial assistance program to be administered by staff of the administrator, subject to limits, eligibility requirements and other conditions established by the advisory committee at the time of such program approval.

Sec. 8. Subsections (j) and (k) of section 32-41cc of the 2014 supplement to the general statutes are repealed and the following is substituted in lieu thereof (*Effective October 1, 2014*):

[(j) Administrative costs shall be paid or reimbursed to the administrator from the Connecticut Bioscience Innovation Fund, provided the total of such administrative costs in any fiscal year shall not exceed five per cent of the total amount of the allotted funding for such fiscal year as determined in the operating budget prepared

pursuant to subsection (i) of this section. Nothing in sections 32-41aa and 32-41bb and this section shall require the administrator to risk or expend the funds of Connecticut Innovations, Incorporated in connection with the administration of the Connecticut Bioscience Innovation Fund.**]**

[(k)**]** (j) Not later than April 15, 2014, and annually thereafter, the administrator shall provide a report of the activities of the Connecticut Bioscience Innovation Fund to the advisory committee for its review and approval. Upon its approval, the advisory committee shall provide such report, in accordance with the provisions of section 11-4a, to the joint standing committees of the General Assembly having cognizance of matters relating to finance, revenue and bonding, appropriations, commerce, public health and higher education. Such report shall contain available information on the status and progress of the operations and funding of the Connecticut Bioscience Innovation Fund and the types, amounts and recipients of financial assistance awarded and any returns on investment.

Sec. 9. Subsection (c) of section 4-28e of the 2014 supplement to the general statutes is repealed and the following is substituted in lieu thereof (*Effective October 1, 2014*):

(c) (1) For the fiscal year ending June 30, 2001, disbursements from the Tobacco Settlement Fund shall be made as follows: (A) To the General Fund in the amount identified as "Transfer from Tobacco Settlement Fund" in the General Fund revenue schedule adopted by the General Assembly; (B) to the Department of Mental Health and Addiction Services for a grant to the regional action councils in the amount of five hundred thousand dollars; and (C) to the Tobacco and Health Trust Fund in an amount equal to nineteen million five hundred thousand dollars.

(2) For the fiscal year ending June 30, 2002, and each fiscal year thereafter, disbursements from the Tobacco Settlement Fund shall be made as follows: (A) To the Tobacco and Health Trust Fund in an amount equal to twelve million dollars, except in the fiscal years

ending June 30, 2014, and June 30, 2015, said disbursement shall be in an amount equal to six million dollars; (B) to the Biomedical Research Trust Fund in an amount equal to four million dollars; (C) to the General Fund in the amount identified as "Transfer from Tobacco Settlement Fund" in the General Fund revenue schedule adopted by the General Assembly; and (D) any remainder to the Tobacco and Health Trust Fund.

(3) For each of the fiscal years ending June 30, 2008, to June 30, 2012, inclusive, the sum of ten million dollars shall be disbursed from the Tobacco Settlement Fund to the **[**Stem Cell**]** Regenerative Medicine Research Fund established by section 19a-32e, as amended by this act, for grants-in-aid to eligible institutions for the purpose of conducting embryonic or human adult stem cell research.

This act shall take effect as follows and shall amend the following sections:		
Section 1	*October 1, 2014*	19a-32d(a)
Sec. 2	*October 1, 2014*	19a-32e
Sec. 3	*October 1, 2014*	19a-32f
Sec. 4	*October 1, 2014*	19a-32g
Sec. 5	*October 1, 2014*	32-41aa
Sec. 6	*October 1, 2014*	32-41bb(e)
Sec. 7	*October 1, 2014*	32-41cc(d) and (e)
Sec. 8	*October 1, 2014*	32-41cc(j) and (k)
Sec. 9	*October 1, 2014*	4-28e(c)

CE *Joint Favorable Subst.*

The following Fiscal Impact Statement and Bill Analysis are prepared for the benefit of the members of the General Assembly, solely for purposes of information, summarization and explanation and do not represent the intent of the General Assembly or either chamber thereof for any purpose. In general, fiscal impacts are based upon a variety of informational sources, including the analyst's professional knowledge. Whenever applicable, agency data is consulted as part of the analysis, however final products do not necessarily reflect an assessment from any specific department.

OFA Fiscal Note

State Impact:

Agency Affected	Fund-Effect	FY 15 $	FY 16 $	FY 17 $
CT Innovations Inc. (quasi-public)	CII Funds - Cost	$1.14 million	$1.14 million	$1.64 million

Municipal Impact: None

Explanation

The bill renames the Stem Cell Research Fund (SCRF) to the Regenerative Medicine Research Fund (RMRF) and expands the type of research eligible for grants-in-aid from the Fund to include regenerative medicine research, as defined in the bill. The bill results in a cost of $1.14 million to Connecticut Innovations, Inc. in FY 15 and FY 16 and a cost of $1.64 million in FY 17.

SUMMARY

Connecticut Innovations, Inc. (CII) serves as the administrative staff to the current advisory committee to the SCRF and continues to do so for the advisory committee of the RMRF under the bill. Additionally, the bill transfers the duties related to assisting the advisory committee in various activities from the Department of Public Health to CII. The estimated administrative cost to CII to administer the fund is $390,000 in FY 15 and FY 16.

The bill also eliminates reimbursements provided to CII related to the administration of the Connecticut Bioscience Innovation Fund

(CBIF).[1] Current law provides up to 5.0% of the allotted funding in the operations budget for each fiscal year to be used for administrative purposes. The loss of reimbursements under the bill results in a cost to CII of $750,000 in FY 15 and 16. The cost will rise to $1.25 million in FY 17 – FY 22. These estimates assume that the operating budget is the same as the bond authorization amount for each fiscal year. [2]

CII is a quasi-public state agency that is financed by loan repayments, investment returns, and fees so any additional costs would not be realized by the state's funds.

sHB 5030, the revised FY 15 budget bill, as favorably reported by the Appropriations Committee, provides $500,000 to CII in FY 15 through a transfer from the Tobacco Settlement Proceeds for administrative and peer review costs associated with RMRF and the CBIF.

Background on Stem Cell Research Fund

Prior to FY 13, SCRF was supported by a transfer from the Tobacco Settlement Fund. In FY 13 - 15, $10 million in bond funding was authorized for SCRF. All funding provided through FY 15 is anticipated to be expended. sSB 29, the revised FY 15 bond bill, as favorably reported by the Finance, Revenue and Bonding Committee, authorizes $10 million in General Obligation bond funds in FY 15 and FY 16 each for the RMRF.

The Out Years

The costs associated with the RMRF continue through FY 2020, the year in which the bill sunsets the program. The costs associated with the CBIF will continue through FY 22, presumably the final year of the program as the bond authorizations are completed in that fiscal year.

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[1] PA 13-239 established the Connecticut Bioscience Innovation Fund to finance projects to improve the delivery of health care services, lower health care costs, and directly or indirectly create bioscience jobs. The Act capitalized the fund by authorizing up to $200 million in GO bonds over 10 years. The State Bond Commission allocated the funds in February 2014.

[2] The bond authorization for FY 13 – 14 is $10 million; FY 15 – 16 is $15 million; FY 17 – 22 is $25 million.

OLR Bill Analysis

sHB 5042

AN ACT CONCERNING THE REGENERATIVE MEDICINE RESEARCH FUND.

SUMMARY:

This bill:

1. broadens the scope of the existing Stem Cell Research Fund to include regenerative medicine;

2. changes the fund's name to the Regenerative Medicine Fund to reflect this new scope;

3. makes corresponding changes to the names and composition of the advisory committee that reviews and approves grants from the fund;

4. adds the Connecticut Innovations, Inc. (CII) chief executive officer (CEO) to the renamed Regenerative Medicine Advisory Committee and designates her the committee's chairperson, replacing the Department of Public Health (DPH) commissioner, who remains on the committee;

5. extends the time for making grants by five years, from 2015 to 2020; and

6. requires the advisory committee to prepare a strategic plan for reviewing peer review committee recommendations about grant applications, awarding grants, and measuring grant recipients' performance.

The bill also makes many technical changes conforming to the fund's new scope and modified administrative structure.

The bill requires the Bioscience Advisory Committee's 13 members to adhere to the Code of Ethics for public officials. The committee oversees the Connecticut Bioscience Innovation Fund, which finances projects to improve the health care delivery system, lower health care costs, and create bioscience jobs. CII manages the fund and, under current law, may tap it to cover the administrative cost of providing this service. The bill eliminates this authority, requiring CII to absorb these costs with its own funds (§§ 6-8).

EFFECTIVE DATE: October 1, 2014

§§ 2 & 9 — RENENERATIVE MEDICINE RESEARCH FUND

The bill renames the Stem Cell Research Fund the Regenerative Medicine Research Fund, reflecting its broader scope encompassing stem cell and regenerative medicine research. The latter encompasses research into the process for creating living, functional tissue to repair or replace tissues or organ functions lost due to aging, disease, damage, or congenital defects. Regenerative medicine includes stem cell research, which the law does not define.

The bill shifts the administrative responsibility for of awarding grants from the DPH commissioner to CII's CEO. CII is the state's quasi-public economic development agency that, among other things, invests venture capital in new and established businesses developing new technologies. The bill also authorizes CII to enter into agreements with various other entities that allow grant recipients to collaborate with other researchers on advance research.

§ 2 — RENENERATIVE MEDICINE RESEARCH ADVISORY COMMMITTEE

Purpose

The bill renames the Stem Cell Research Advisory Committee the Regenerative Medicine Advisory Committee. The committee's current stem cell-related duties include developing grant applications and requiring eligible institutions seeking research grants to describe themselves, their plans for stem cell research, and the possible financial

benefits to the state resulting from their research.

The bill requires the renamed committee to perform these duties with respect to regenerative medicine research. It also requires the committee to direct CII's CEO, instead of the DPH commissioner, on awarding grants, which it must do after considering the peer review committee's recommendations.

Composition

The bill retains the structure of the current 18-member committee, but changes the members' qualification to reflect the inclusion of regenerative medicine research. The bill keeps the DPH commissioner on the committee but removes her as chairperson. It adds CII's CEO (or her designee) to the renamed committee, increasing its membership to 19, and making the CEO or her designee the board's chairperson.

The bill keeps the current appointing authorities, but changes the qualifications of the members they must appoint to reflect the inclusion of regenerative medicine research.

1. The governor continues to appoint four members, but two must have background and experience in embryonic stem cell or regenerative medicine research and two must have background and experience in business, law, or ethics.

2. The Senate president pro tempore and the House speaker each continue to appoint two members, but they must have background and experience in private-sector regenerative medicine research and development (R&D) instead of embryonic stem cell R&D.

3. The House and Senate majority leaders each continue to appoint two members, but they must be academic researchers specializing in regenerative medicine, instead of stem cell, research.

4. The Senate and House minority leaders continue to appoint two

members, but (1) the former must appoint someone with background and experience in public- or private-sector regenerative medicine, instead of stem cell, research and development and (2) the latter must continue to appoint someone with a business or financial investment background and experience.

The bill makes conforming technical changes to the board's makeup, member terms, and operations, including the requirement prohibiting a member from reviewing or considering a grant application in which he or she has a financial stake.

Duties

The bill realigns the board's duties to encompass regenerative medicine research and adds a new one. It requires the committee to prepare a comprehensive strategic plan, including awarding grants. At a minimum, the plan must identify methods or strategies to achieve the fund's economic development objectives, build capacity for innovation, and sustain the money invested in the fund.

The bill also requires the committee to work with CII, instead of the DPH commissioner, to develop a program that encourages the development of nonappropriated state funds and promotes regenerative medicine, among other things.

CII Support

Under the bill, CII provides administrative support to the fund, which includes helping the committee (1) develop and review grant applications and (2) prepare and execute funding agreements. But, under the bill, CII must also help the committee evaluate the grant-funded research's economic impact.

Specifically, CII must help the committee develop performance measures and data collection systems. The data must include each recipient's employment statistics; its business accomplishments and outcomes; peer-reviewed articles and published papers; partnerships and collaborations with other entities; licenses, patents, and invention

disclosures; intellectual property developed with the grant that was put to commercial use; and research funds from other sources.

§ 4 — REGENERATIVE MEDICINE RESEARCH PEER REVIEW COMMITTEE

Purpose

The bill renames the Stem Cell Research Peer Review Committee the Regenerative Medicine Research Peer Review Committee, changing its composition and purpose to reflect the inclusion of regenerative medicine research.

Composition

The bill changes the qualifications and appointing authority of the committee members, also reflecting its emphasis on regenerative medicine research. It ends the DPH's commissioner authority to appoint people to the five-member committee after September 30, 2014. Until that date, the commissioner must fill any vacancies by appointing members with a background and knowledge related to regenerative medicine research, instead of stem cell research.

The law's current requirements regarding attendance, ethics, and conflicts of interest apply to these members. As under current law, these DPH-appointed members serve four-year terms. But they cannot serve consecutive four-year terms nor concurrently serve on the Regenerative Medicine Advisory Committee.

The DPH-appointed members may continue serving on the committee until their terms expire. However, on October 1, 2014, appointing power shifts to the CII CEO and her appointees must meet the bill's requirements for background and knowledge related to regenerative medicine. The CII appointees serve four- year terms, except for the first three, who serve two-year terms. Like the DPH appointees, these appointees cannot serve consecutive four-year terms nor concurrently serve on the Regenerative Medicine Advisory Committee. The law's current requirements regarding attendance, ethics, and conflicts of interest apply to them.

Duties

Under current law, before the advisory committee awards grants, the peer review committee considers grant applications and makes recommendations to the DPH commissioner and the advisory committee about their ethical and scientific merit. Under the bill, the peer review committee must make recommendations to CII with respect to regenerative medicine research.

The bill does not extend to the reconstituted committee the requirement that its members make themselves aware of the National Academies Guidelines for Human Embryonic Stem Cell Research and make recommendations to the advisory committee and the DPH commissioner about adopting any or all of these guidelines in regulations.

Compensation

The bill changes the funding source for compensating committee members for their reviews. Under current law, the funds come from the Stem Cell Research Fund, and the compensation rate is determined by the DPH commissioner, in consultation with the Department of Administrative Services and the Office of Policy and Management. Under the bill, CII compensates the members with its funds at a rate its board of directors sets.

COMMITTEE ACTION

Commerce Committee

Joint Favorable Substitute
Yea 17 Nay 0 (03/20/2014)